DEPARTMENT OF THE NAVY



BUREAU OF MEDICINE AND SURGERY 2300 E STREET NW WASHINGTON DC 20372-5300

IN REPLY REFER TO

3900 Ser M00R/09UM00R189 19 June 2009

From: Chief, Bureau of Medicine and Surgery

Subj: DEPARTMENT OF THE NAVY HUMAN RESEARCH PROTECTION PROGRAM (DON HRPP) GUIDANCE: USE OF TELECONFERENCE FOR INSTITUTIONAL

REVIEW BOARD (IRB) MEETINGS

Ref: (a) Code of Federal Regulations 32 CFR 219

- 1. The Department of Defense regulations in reference (a), "the Common Rule," require IRBs to "review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas."
- 2. Video-conferencing and teleconferencing should be used only on rare occasions and when a conventional gathering of the IRB members cannot be arranged, rather than on a regular basis.
- 3. While DON HRPP strongly recommends IRB meetings take place with participating IRB members physically present, we will recognize as "convened" those IRB meetings conducted, in whole or in part, via video-conference or telephone conference call, as long as:
- a. Each participating IRB member has received all relevant materials with sufficient time for review prior to the meeting;
- b. Each participating IRB member is able to participate actively in the real-time discussion of the relevant protocols; and,
 - c. All usual requirements, such as those regarding quorum and membership, are met.
- 4. Other forms of remote interaction or voting (for example, e-mail, instant message, on-line forums, or chat) do not meet the conditions and are not permissible substitutes for direct participation in an IRB meeting. Written reviews or other contributions from absent members similarly do not constitute active participation in a meeting.
- 5. However, DON HRPP recognizes the value of such contributions for deliberations by a properly constituted convened IRB. Therefore, IRBs may invite individuals as consultants to provide expertise to assist the IRB in its review, and these individuals may participate via video-conference or teleconference. These individuals may not vote as per ref (a).

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- 6. In situations where video-conferencing or teleconferencing are used the meeting minutes should document:
 - a. Which members attended via these methods and for which portions of the meeting;
- b. That such members received all relevant materials with sufficient time for review prior to the meeting; and
 - c. The rationale for why such members were unable to attend in person.
- 7. Please forward this letter to your IRB Chair and IRB Administrator. If there are any questions, please contact me at 202-762-0161 or at human.research@rned.navv.mil.

M. L. Richard By Direction

Distribution:

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